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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,494	04/19/2004	Ken Xiao Kang Zhang	S63.2-11346-US01	3474
490 7590 09/17/2007 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER HUSON, MONICA ANNE	
			ART UNIT 1732	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/827,494

Applicant(s)

ZHANG ET AL.

Examiner

Monica A. Huson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

This office action is in response to the Amendment filed 2 July 2007.

The restriction requirement is withdrawn due to applicant's amendment.

#### ***Claim Objections***

Claim 3 is objected to because of the following informalities: As amended, it is essentially a duplicate of Claim 20. Appropriate correction is required.

#### ***Specification***

The amendment filed 2 July 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: using a heated *liquid* fluid (emphasis added).

Applicant is required to cancel the new matter in the reply to this Office Action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17, 21, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original support for applicant's amended claims which require a heated *liquid* fluid (emphasis added).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is unclear how the subject matter of claims 2-16 further define the methodical, step-wise invention of independent Claim 17. The examiner cannot find any method limitations in Claims 2-16.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 20, 22, 2-5, 7-9, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonhardt (U.S. Patent 5,522,961). Regarding Claim 17, Leonhardt shows that it is known to carry out a method of forming a medical device (Abstract) comprising the steps of placing a parison in a mold having a cavity with a wall form substantially conforming to the desired shape of said device (Column 2, lines 41-43); immersing the mold in a heated liquid fluid to heat the parison (Column 2, lines 43-45; heated liquid fluid=water); pressurizing the parison to radially expand the parison to contact the walls of the mold cavity (Column 2, lines 47-51), wherein the mold cavity wall contains at least one through-hole therein through which the heated liquid fluid enters the mold cavity to directly contact the parison when the mold is immersed in the heated fluid and through which heated liquid fluid that has entered the mold cavity is expelled therefrom when the parison is radially expanded (Column 3, lines 60-64; It is interpreted that the heated liquid fluid enters through elements 46, and is expelled back through elements 46 when the parison is expanded, along with any air existing in the mold.).

Regarding Claims 20 and 3, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including a method wherein the mold cavity wall contains a plurality of said through-holes therein (Figure 2, elements 46).

Regarding Claim 22, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including a method wherein the heated liquid fluid is water (Column 4, lines 27-30).

Regarding Claims 2, 4, and 5, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including a method wherein the through holes are formed as longitudinally-oriented slots which are arranged in a plurality of circumferentially spaced columns (Figure 2, elements 46; the elements 46 are slot-shaped in the longitudinal direction, left to right, forming columns of space around the circumference of the mold).

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Regarding Claims 7-8, Leonhardt shows the process as claimed as discussed in the rejection of Claims 17 and 5 above, including showing four of said circumferentially spaced column of slots (Figure 2, elements 46; note that there are 4 elements 46).

Regarding Claim 9, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including a method wherein the at least one through-hole has a dimension at the mold cavity wall inner surface which does not allow substantial penetration of the parison material therethrough when heated to the temperature of the heated fluid and pressurized at a pressure sufficient to expand the parison to contract the mold cavity wall (Column 4, lines 30-39; It is interpreted that the elements 46 are large enough for the passage of heated fluid and air, however not large enough to warrant concern by Leonhardt that the parison would be expanded through the elements 46).

Regarding Claims 13-14, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including a method wherein the cavity has a diameter is 10-13mm (Column 4, lines 4-7).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 10-12, and 15-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt.

Regarding Claim 6, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including showing circumferentially-placed slots. He does not particularly show the slots being staggered longitudinally. However, the particular placement of an element is known to be an obvious matter of design choice (See MPEP 2144.04 (IV)(C)). Therefore, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to rearrange the slots of Leonhardt to be longitudinally staggered and circumferentially-placed, in order to design the mold according to customer specifications (note that Leonhardt teaches varying the design of the slots, as some elements 46 are longitudinally oriented and other elements 46 are vertically oriented).

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Regarding Claims 10-12, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including a method wherein a mold includes a through hole. He does not particularly disclose a shape or pattern involving the through hole. However, changes in shape are known to be a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration was significant (See MPEP 2144.04 (IV)(B)). Therefore, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use any particular shape and pattern associated with the through hole in order to accommodate particular customer specifications.

Regarding Claims 15-16, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, including showing a cavity portion with a through hole with a certain dimension. He does not discuss exclusive dimensions of the hole, however, where the general conditions of a claim (a through hole with an existing dimension relative to a catheter mold) are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (See MPEP 2144.05 (II)(A)). Therefore, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to arrive at optimal dimensions for the through hole, such as those claimed, in order to achieve optimal fluid transfer between the mold, parison, and fluid environment.

Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt, in view of Gass-Erb (U.S. Patent 3,766,358).

Regarding Claim 18, Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, but he does not show agitating the fluid while the mold is immersed therein. Gass-Erb shows that it is known to carry out a method including a step comprising agitating a heated fluid while an object is immersed therein (Column 7, lines 32-35). Gass-Erb and Leonhardt are combinable because they are concerned with a similar technical field, namely, methods of heating objects using immersion techniques. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Gass-Erb's agitated heating bath in Leonhardt's molding process in order to provide equal temperature distribution throughout the heating fluid (See Gass-Erb, Column 1, lines 50-54).

Regarding Claim 21, Leonhardt shows that it is known to carry out a method of blowing a balloon (Abstract) by immersing a mold containing a hollow parison of thermoplastic polymer material into a heated liquid fluid and pressurizing the parison (Column 2, lines 41-45, 47-51). Leonhardt does not show agitating the fluid while the mold is immersed therein. Gass-Erb

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shows that it is known to carry out a method including a step comprising agitating a heated liquid fluid while an object is immersed therein (Column 7, lines 32-35). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Gass-Erb's agitated heating bath in Leonhardt's molding process in order to provide equal temperature distribution throughout the heating fluid (See Gass-Erb, Column 1, lines 50-54).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt, in view of Garrett (U.S. Patent 6,073,540). Leonhardt shows the process as claimed as discussed in the rejection of Claim 17 above, but he does not show vibrating the molding apparatus while the mold is immersed in the heated fluid. Garrett shows that it is known to carry out a method including vibrating the article while it is immersed in the heated fluid (Column 3, lines 1-8). Garrett and Leonhardt are combinable because they are concerned with a similar technical field, namely, methods of heating objects using fluid. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Garrett's article vibration technique during Leonhardt's molding process in order to effect more uniform heat transfer (See Garrett, Column 3, lines 6-7).

### ***Response to Arguments***

Applicant's arguments filed 2 July 2007 have been fully considered but they are not persuasive.

The rejection of claims 17 and 20 in view of Mahoney is overcome by applicant's amendment.

Applicant contends that Leonhardt does not show the claimed invention because his holes are not sized or channeled in a way that permits water to enter the cavity and contact the parison. This is not persuasive because although Leonhardt clearly mentions that the elements 46 allow air to pass out of the mold, there is no evidence or suggestion that the holes would prevent passage of water through the mold to contact the parison while the mold is submerged. It is noted that attorney's arguments cannot take the place of evidence in the record (See MPEP 2145). It is maintained that water would pass through the holes 46 while the mold is submerged, and when the parison is expanded, air would escape from the mold, as well as any water left between the parison and the mold.

Applicant contends that Leonhardt and Gass-Erb do not suggest the claimed invention because Gass-Erb does not show anything analogous to a balloon mold. This is not persuasive because Gass-Erb was not cited to show a balloon mold immersed in a heated fluid. Gass-Erb shows an object immersed in a heated liquid, wherein agitation is performed while the object is

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immersed in the heated liquid. Since Leonhardt shows that a balloon mold can be immersed in a heated liquid, one of ordinary skill in the art would easily recognize that the balloon mold could be the "object" which is immersed in Gass-Erb's agitated heated liquid. It is maintained that Leonhardt and Gass-Erb clearly suggest the claimed subject matter of claims 18 and 21.

In response to applicant's argument that Leonhardt and Garrett is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Leonhardt and Garrett are both reasonably pertinent to the particular problem of most efficiently heating an immersed object using a heated liquid bath.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Monica A. Huson". The signature is fluid and cursive, with the first name "Monica" being more prominent than the last name "Huson".

Monica A Huson

September 7, 2007